Int'l Appl. No. : PCT/NZ03/00115 Int'l Filing Date : June 5, 2003

## AMENDMENTS TO THE CLAIMS

- 1. (Currently Amended) A process for administering one or more biologically active agents to an animal, comprising administering to said animal on a single occasion progressively increasing doses of said one or more biologically active agents which are released in a form that releases progressively increasing doses of said one or more biologically active agents over a predetermined period of time-from a delivery means which is administered to an animal on a single occasion.
- 2. (Currently Amended) A process as claimed in claim 1 wherein said one or more biologically active agents are selected from the group consisting list of: antibiotics, anthelmintics antihelminthics, peptides, proteins, carbohydrates, DNA, RNA, hormones, neutraceuticals, vitamins, trace-elements, immunising immunizing agents or and any combination thereof.
- 3. (Currently Amended) A process as claimed in either claim 1 of claim 2 wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.
- 4. (Currently Amended) A process as claimed in any one of claims 1 to 3 claim 1 wherein the progressively increasing doses comprise sequentially doubling doses of said biologically active agents, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.
- 5. (Currently Amended) A process as claimed in any one of claims 1 to 4 claim 1 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from the group consisting of: hours, days, weeks, or months and or any combination thereof.
- 6. (Currently Amended) A process as claimed in any one of claims 1-to 5-claim 1 wherein said one or more biologically active agents is an immunising-immunizing agent and wherein said process comprises the administration to said animal of progressively increasing doses of one or more immunising-immunizing agents which are released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
- 7. (Original) A process as claimed in claim 6 wherein said one or more immunising immunizing agents comprise an antigen or combination of antigens.
- 8. (Currently Amended) A process as claimed in claim 6 or claim 7 wherein said one or more immunizing agents comprise a vaccine or combination of vaccines.

Int'l Appl. No. : PCT/NZ03/00115 Int'l Filing Date : June 5, 2003

9. (Currently Amended) A process as claimed in any one of claims 6 to 8 claim 6 wherein said one or more immunising immunizing agents are selected from the group consisting of: molecules that will induce protective immunity against a disease causing organism, or molecules that will induce functional immunity, and or any combination thereof.

10. (Currently Amended) A process as claimed in any one of claims 6 to 9 claim 6 wherein the progressively increasing doses of said one or more immunising immunizing agents are in the range of from about 0. 1 μg to 1000 μg.

## 11. (Canceled)

- 12. (Currently Amended) A biologically active agent delivery composition comprising one or more biologically active agents whereby said composition comprises means to enable is configured to deliver progressively increasing doses of said one or more biologically active agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion administration.
- 13. (Currently Amended) A biologically active agent delivery composition as claimed in claim 12 wherein said one or more biologically active agents are selected from the list group consisting of: antibiotics, anthelminties antihelminthics, peptides, proteins, carbohydrates, DNA, RNA, hormones, neutraceuticals, vitamins, trace-elements, immunising immunizing agents or and any combination thereof.
- 14. (Currently Amended) A biologically active agent delivery composition as claimed in either claim 12 of claim 13 wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.
- 15. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 14 claim 12 wherein the progressively increasing doses comprise sequentially doubling doses of biologically active agents, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.
- 16. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 15 claim 12 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from the group consisting of: hours, days, weeks, or months or and any combination thereof.
- 17. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 16 claim 12 wherein said one or more biologically active

Int'l Appl. No. Int'l Filing Date PCT/NZ03/00115

I Filing Date : June 5, 2003

agents is an immunising-immunizing agent and wherein said delivery composition comprises means to enable enables progressively increasing doses of one or more immunising agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.

- 18. (Original) A biologically active agent delivery composition as claimed in claim 17 wherein said one or more immunising immunizing agents comprise an antigen or combination of antigens.
- 19. (Currently Amended) A biologically active agent delivery composition as claimed in claim 17 or claim 18 wherein said one or more immunising—immunizing agents comprise a vaccine or combination of vaccines.
- 20. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 17 to 19 claim 17 wherein said one or more immunising immunizing agents are selected from the group consisting of: molecules that will induce protective immunity against a disease causing organism, of molecules that will induce functional immunity of and any combination thereof.
- 21. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 17 to 20 claim 17 wherein the progressively increasing doses of said one or more immunising immunizing agents are in the range of from about 0.1 µg to 1000 µg.
- 22. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 21 claim 12 wherein the delivery composition comprises two or more types of microspheres or microparticles, wherein each type of microsphere or microparticle containing contains a different dose of one or more biologically active agents and wherein said microspheres or microparticles comprise comprising biodegradable material which will degrade over a known time period so that the lowest dose of biologically active agents is released from a first type of microsphere or microparticle at a set time after administration, followed by the next highest dose of biologically active agents at the next predetermined time etc.
- 23. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 22 claim 12 wherein the delivery composition is located within a delivery means comprising a bioerodable device that releases progressively increasing amounts of the biologically active agents as it erodes.

Int'l Appl. No. : PCT/NZ03/00115 Int'l Filing Date : June 5, 2003

- 24. (Currently Amended) A biologically active agent delivery composition as claimed in any one of claims 12 to 23 claim 12 wherein the delivery composition is administered to an animal by way of injection, ingestion or implantation.
- 25. (Original) A biologically active agent delivery composition as claimed in claim 24 wherein the administration of the delivery composition takes place shortly after birth of an animal, or when maternally-derived antibody has decreased sufficiently for the young animal to be able to respond to the vaccination, and provides immunity without the need for further booster administration.
- 26. (Currently Amended) A delivery means for use, a process as described in any one of claims 1 to 11 wherein the delivery composition is located within comprising a multicompartmental capsule containing comprising a plurality of compartments with progressively increasing doses of one or more biologically active agents within the compartments, said delivery means capsule comprising an outer wall made of a at least one biodegradable substance which degrades over a pre-set period of time to release the smallest dose of biologically active agents, and one or more inner compartmental walls made of the same or different material that degrade over a longer period of time to release progressively increasing pulses of the biologically active agents
- 27. (Currently Amended) A delivery means capsule as claimed in claim 26 wherein the biodegradable material of the outer wall is be selected from the group comprising consisting of: cholesterol/lecithin, polylactide, and/or polyglycolide copolymers, one or more of a number of cellulose polymers, polyacrylic acid, polymethylmethacrylate, cross-linked polyacrylic acid, polyeaprolactone, polyvinylpyrrolidine, polyvinylalcohol, polyethylene glycol, agarose, DEAE dextran microspheres, starch microspheres, and/or albumin microspheres, or gelatine gelatin microspheres, or and any combination thereof.
- 28. (Currently Amended) A delivery means capsule as claimed in claim 26 or claim 27 wherein the pre-set period of time within which the outer wall and inner compartmental walls degrade may be selected from the group consisting of: hours, days, weeks, or and months.

## 29-30 (Cancelled)

31. **(NEW)** The process of claim 4 wherein said sequentially increasing doses are 25, 50, 75, 100 or 4, 8, 32, 150 active units.

Int'l Appl. No. Int'l Filing Date

PCT/NZ03/00115 June 5, 2003

32. **(NEW)** The process of claim 15 wherein said sequentially increasing doses are 25, 50, 75, 100 or 4, 8, 32, 150 active units.